

REMARKS

The April 14, 2009 Office Action addresses claims 1, 5, 6, 9, 15-19, 23, 24, 26, 28-30 and 48-104. In this action, the Examiner withdraws claims 1, 5-6, 9, 15-17, 19, 23-24, 26, 29-30, 48-49, 50-52, 57-73, and 97-104 as being directed to inventions that are independent or distinct from the invention originally claimed. As detailed below, Applicants respectfully disagree with the Examiner and request rejoinder and examination of these claims. As discussed below, each of these claims is directed to an invention that has been examined during the prosecution of the application.

The Examiner also objects to claims 74-75, 77, 79, 83-85, 87-89, and 91 pursuant to 37 CFR 1.75(c), as being of improper form for failing to further limit the subject matter of a previous claim. As detailed below, Applicants disagree with these objections because each of these dependent claims clearly limits the scope of independent claim 53.

The Examiner also rejects claims 53-56 and 74-77 pursuant to 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. While Applicants disagree with this rejection, independent claim 53 is hereby amended solely for the purpose of expediting prosecution and obviating this rejection.

The Examiner further rejects claims 78-95 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,159,236 of Biel, and claims 53-56, 74-77, and 96 pursuant to 35 U.S.C. § 103(a) as being unpatentable over Biel in view of U.S. Patent Publication No. 2002/0029071 of Whitehurst. As discussed in detail below, the claims distinguish patentably over the Biel reference as well as the combination of Biel and Whitehurst.

Thus, in view of the following, Applicants respectfully request reconsideration and allowance of claims 1, 5, 6, 9, 15-17, 19, 23, 24, 26, 28-30, 48-52, 57-73, and 97-104.

Claim Amendments

Applicants hereby amend independent claim 53 to recite a step of irradiating at least a portion of tissue in an oral cavity with electromagnetic radiation having a power density in a range of from about 1 W/cm² to about 10 W/cm².

Support for this amendment can be found throughout the specification as filed, for example, at paragraph [0015]. More specifically, paragraph [0015] teaches:

[015] In a related aspect, the biostimulating effect is achieved by irradiating the oral cavity during multiple treatment sessions with a radiation power in range of about 1 mW/cm² to about 10 W/cm² so as to deposit a radiation dose in a range of about 1 Joules/cm² to about 1000 Joules/cm², **and more preferably in a range of about 10 Joules/cm² to about 100 Joules/cm², in the irradiated tissue. The treatment sessions, each of which can last for about 10 seconds to about 1000 seconds**, or longer if needed, can be repeated until a total therapeutic dose of radiation, e.g., a total radiation dose in a range of about X Joules/cm² to about X Joules/cm², and more preferably a total dose in range of about X Joules/cm² about X Joules/cm², is deposited in the oral cavity tissue. (Emphasis added)

Hence, for a disclosed treatment time of 10 seconds and the preferred radiation dose of from about 10 Joules/cm² to about 100 Joules/cm², the radiation power ranges from about 1 W/cm² (10 Joules/cm²/10 second = 1 W/cm²) to about 10 W/cm² (100 Joules/cm²/10 sec = 10W/cm²). Thus, no new matter is added.

Election/Restrictions

The Examiner requires withdrawal of numerous claims based on new claims submitted in Applicants' previous response and also based on previously presented amendments (See Office Action, pp. 2-3). For example, the Examiner requires withdrawal of claim 97 and claims depending therefrom (i.e., claims 23-24, 26, 29-30, 50-52, and 98-104).

Independent claim 97 recites:

A method of treating a subject's blood, comprising:
 exposing at least a portion of a subject's oral cavity to radiation having wavelength components in a range of about 280 nm to about 1800 nm to irradiate blood flowing in vasculature of the oral cavity;
 irradiating the oral cavity with said radiation during separate treatment sessions such that a radiation power in a range of about 1 mW to about 10 W is administered to the oral cavity during each treatment session; and
 irradiating the subject's oral cavity for a sufficiently long time so as to expose substantially an entire volume of the subject's blood to said radiation in one or more treatment sessions.

In responding to the previous Office action, new claim 97 was presented that generally corresponds to the subject matter of original independent claim 20 and dependent claim 27.

The original claims 20 and 27, as well as original claims 21-26 and 28-30 that were dependent on claim 20, have been examined throughout the course of prosecution. As such, Applicants respectfully submit that the withdrawal of claim 97 and its dependent claims is improper. Applicants respectfully request rejoinder and examination of independent claim 97 and dependent claims 23-24, 26, 29-30, 50-52, and 98-104.

The Examiner also withdraws claims 1, 5-6, 9, 15-17, 19, 48-49, and 57-73 due to the amendments introduced into independent claim 1 in the Response to the previous Office Action. That is, in the previous Response to Office Action, Applicants amended claim 1 to recite "[a] method for providing a dermatological or cosmetic treatment" as opposed to methods for reducing or eliminating pathogens located in the oral cavity and for biostimulation.

Again, Applicants respectfully disagree with the Examiner's rationale for withdrawal. At least some of the original claims were directed to methods for dermatological and/or cosmetic treatments. For example, the original claim 45 was directed to "[A] method of treating facial tissue," and the original claim 46 was directed to "[A] method of improving the appearance of skin." These claims were examined prior to being cancelled. In the Office Action issued on December 13, 2005, the Examiner did not require restriction of these claims but rather examined them.

Accordingly, Applicants respectfully request rejoinder and examination of independent claims 1 and 97 as well as all claims depending therefrom.

Claim Objections

The Examiner objects to dependent claims 74-75, 77, 79, 83-85, 87-89 and 91 pursuant to 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. More specifically, the Examiner argues that “[t]hese claims do not provide an actual method step and only relate to the desired result or effect.” Office Action, p. 4.

Applicants respectfully disagree. Claims 74-75 depend from independent claim 53. Claim 53 recites a method of biostimulation, which causes a biostimulation effect. Claims 74 and 75 recite specific examples of such a biostimulation effect, and hence limit the subject matter of claim 53. Similarly, claim 77 indirectly depends from claim 53 and clearly limits the subject matter of the intervening claim 76. Similarly, claims 79, 83-85, 87-89, and 91 clearly limit their corresponding independent claims.

Thus, claims 74-75, 77, 79, 83-85, 87-89 and 91 are proper and the pending objections should be removed.

Claim Rejections Pursuant to 35 U.S.C. § 112

The Examiner rejects claims 53-56 and 74-77 pursuant to 35 U.S.C. § 112, *first paragraph*, as failing to comply with the written description requirement. That is, the Examiner argues that independent claim 53 contains subject matter not found in the original specification. More specifically, the Examiner argues that “[t]he specific power intensity of equal or greater than about 1 W/cm² is new matter not in the original disclosure.” Office Action, p. 4.

Applicants disagree with this rejection as Applicants clearly indicated support for a specific power density of equal or greater than about 1 W/cm² in the previous response. However, in order to expedite prosecution, Applicants hereby amend independent claim 53 to recite a step of irradiating at least a portion of tissue in an oral cavity with electromagnetic radiation having a power density *in a range of from* about 1 W/cm² *to about* 10 W/cm². As

detailed above, explicit support for this amendment is provided in paragraph [0015] of the specification as originally filed.

Thus, the rejections of independent claim 53 and dependent claims 54-56 and 74-77 are hereby obviated.

Claim Rejections Pursuant to 35 U.S.C. § 102

The Examiner rejects claims 78-95 pursuant to 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,159,236 to Biel ("Biel").

Independent claim 78 recites a biostimulation method, which includes inserting at least a portion of a phototherapy applicator into an oral cavity, and irradiating an area of tissue in the oral cavity with radiation from the phototherapy applicator. The claim further recites that the radiation includes multiple distinct wavelength bands corresponding to one or more absorption spectra of one or more light acceptors in the oral cavity or in tissue associated with the oral cavity wherein said one or more light acceptors absorbs at least one radiation wavelength in each of said bands. The claim further recites that the area of tissue is irradiated *concurrently with said multiple wavelength bands* so as to provide a desired biostimulation.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See M.P.E.P. § 2131.

Biel teaches a medical device having a tube and expandable member and one or more light sources disposed in an elongate member disposed in the tube. The light sources emit energy for photodynamic therapy through a window to the treatment area.

In contrast to independent claim 78, Biel does not disclose, teach, or suggest a method wherein the area of tissue is irradiated *concurrently with multiple wavelength bands* so as to provide a desired biostimulation. There is no indication in Biel that one or more light emitting members operate at different wavelength bands, and Biel certainly does not teach that an area of

tissue would concurrently be illuminated by multiple wavelength bands. In fact, there is no reason to believe that Biel would need to illuminate a tissue area *concurrently* with multiple wavelength bands. Biel's device is used for performing photodynamic therapy in which a photosensitizing drug administered to a patient is typically illuminated with a single wavelength band corresponding to a wavelength absorbed by the drug.

Thus, Biel does not anticipate independent claim 78. As indicated, the Examiner also rejects claims 79-95 pursuant to 35 U.S.C. § 102(b) as being anticipated by Biel. Claims 79-95 depend from independent claim 78. Thus, claims 79-95 are also allowable at least because they depend from an allowable base claim.

Claim Rejections Pursuant to 35 U.S.C. § 103

The Examiner rejects claims 53-56, 74-77, and 96 pursuant to 35 U.S.C. § 103(a) as being obvious over Biel in view of U.S. Patent Publication No. 2002/0029071 to Whitehurst ("Whitehurst"). More specifically, the Examiner argues that Biel purportedly teaches each step of independent claim 53 except that "Biel is silent with regards to a power intensity equal to or greater than 1 W/cm^2 ." Office Action, p. 8. The Examiner provide Whitehurst as purportedly curing this deficiency.

Independent claim 53 recites a method of biostimulation via an oral cavity, which includes irradiating at least a portion of tissue in an oral cavity with electromagnetic radiation having a power density, as amended, in a range of about 1 W/cm^2 to about 10 W/cm^2 and at least one wavelength corresponding to an absorption band of an endogenous photoreactive substance located in the portion of tissue. The claim further recites that the photoreactive substance absorbs sufficient electromagnetic radiation to cause the selected biostimulation effect.

As conceded by the Examiner, Biel does not disclose a power density in a range of about 1 W/cm^2 to about 10 W/cm^2 . Rather, Biel teaches the use of a power density in a range of 0 to 150 mW/cm^2 , well below the claimed lower limit of 1 W/cm^2 .

The Examiner provides Whitehurst as purportedly curing this deficiency. Whitehurst provides a therapeutic light source, for example for photodynamic therapy (PDT), which

comprises an air-cooled array of LED's. Whitehurst teaches that the array operates "in the treatment field of "at least 30 mW/cm^2 in the red region of the spectrum and at least 10 mW/cm^2 in the blue region." Paragraph [0044].

The Examiner argues that Whitehurst teaching of *at least 30 mW/cm^2* overlaps the claimed range and thus cures the deficiencies of Biel. Applicants disagree. A device operating at 30 mW/cm^2 (i.e., 0.030 W/cm^2) is operating well below the lower limit of 1 W/cm^2 . In fact, the highest power density disclosed by Whitehurst is 45 mW/cm^2 (i.e., 0.045 W/cm^2), which is also significantly less than 1 W/cm^2 . See Paragraph [0045] Nor is there any examples in Whitehurst in which the applied power density would even approach 1 W/cm^2 .

Further, similar to Biel, Whitehurst is directed to *photodynamic therapy* in which the concentration of the administered drug and/or its radiation absorbing properties would obviate the need to apply a power density as high as 1 W/cm^2 to the patient. In fact, for a power density above 1 W/cm^2 the tissue can be thermally damaged because of overheating due to absorption in the PDT drug. Thus, independent claim 53 is allowable over any combination of Biel and/or Whitehurst.

The Examiner also rejects claims 54-56, 74-77, and 96 pursuant to 35 U.S.C. § 103(a) as being obvious over Biel in view of Whitehurst. These claims all depend from independent claim 53, and are therefore also allowable at least because they depend from an allowable base claim.

Conclusion

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

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